

REMARKS

Status of the claims

Claims 1-15 were pending in this application with claims 1-5, 8 and 9 having been withdrawn from active consideration by the Examiner. With this submission, the withdrawn claims have been canceled without prejudice to prosecution of the canceled subject matter in a continuation application. No claims have been amended or newly added herewith. Therefore, upon entry of this amendment, claims 6, 7, and 10-15 will remain pending and under active consideration.

Applicants respectfully request reconsideration of the present application in view of the reasons that follow. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

Claim rejections under 35 U.S.C. § 103

Claims 6, 7, 13, and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over MacDonald “Bioartificial livers” in view of “Minuth” (US 6187053), and as being unpatentable over “Martinez” (US 6582955) in view of Minuth. Claims 6, 7, and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez in view of Minuth, Nunez (US 6840958) and/or Kapadia (US 4816028). Also, Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez in view of Minuth and Ghezzi (US 5194157).

Applicants thank the Examiner for withdrawing the rejection under 35 U.S.C. § 102 involving MacDonald and Martinez in view of the last-filed arguments. However, the claims now stand rejected in view of a combination of MacDonald or Martinez in view of Minuth (and other secondary references). The Examiner alleges that Minuth “clearly addresses the deficiencies of the MacDonald and Martinez references by indicating that is known in the art to utilize biodegradable polylactide materials in the construction of bioreactor supports.” Office Action, page 11. The Examiner draws that conclusion from an inference that since Minuth states

“that polylactide fibers work to promote natural cell growth during the culturing process, it would have been obvious to utilize these fibers in the apparatus of MacDonald and Martinez in order to facilitate cell attachment and expansion.” Because Applicants respectfully disagree with the Examiner’s inference, Applicants respectfully traverse this ground of rejection.

First, Applicants respectfully submit that the Examiner’s characterization of Minuth’s “perfusion chamber” as a “bioreactor” is improper. In fact, given the art-recognized definition of a “bioreactor,” Minuth is properly silent with respect to a “bioreactor.” While Minuth does recite a “perfusion chamber,” Applicants submit that bioreactors entail more than a mere perfusion chamber. Indeed, the perfusion chambers of Minuth are solely for the purpose of producing an implant, which is then removed and implanted in a body. “Bioreactors” as defined in the art, and as designed by the present invention, are designed to provide *sustained, long-term*, organ function (*e.g.*, liver function). Bioreactors thus face a host of technical issues—*e.g.*, waste removal, gas and nutrient permeation—that are not of necessary consideration when growing tissue in a perfusion chamber for a brief period before transplantation *in vivo*. What is more, the tissue implants of Minuth, even if allegedly “three-dimensional,” are at best nominally so. In fact, one of ordinary skill in the art would recognize that the perfusion chambers of Minuth could simply not produce larger “organ-like” structures, for lacking adequate solutions to the technical issues noted above. Hence, at least because (1) Minuth’s perfusion chamber technology can not be readily used for applications that require bioreactors and (2) bioreactors address technical challenges that do not arise with “perfusion chambers,” Applicants respectfully submit that the combination of the references is improper.

Second, even if the combination *per se* is deemed proper, Minuth does *not* teach biodegradable fibers that are coated upon a *carrier* as asserted by the Examiner. Office Action, page 3, second paragraph. To the contrary, all of the written description and figures in Minuth teach biodegradable fibers that are coated upon a *membrane or cell base*. Col. 3, second paragraph. The Minuth figures (*e.g.*, Figure 5) also leave no doubt that the biodegradable fibers

of the coating do not even touch the carrier, which is separated from the coating by a cell base “membrane.”

Notably, the *carrier* of Minuth consists of non-biodegradable material, specifically, “net-like or screen-like material of metal or plastic with sufficient strength.” Col 2, lines 63-65. By contrast, the “carrier” of the present invention (*i.e.*, the woven fabric) *does* comprise a biodegradable polymer.

Third, the carrier of Minuth does *not* have a three-dimensional skeleton as does the woven fabric of the claimed invention. Col. 1, lines 32-35. Even if the Examiner interprets the coating *per se* of Minuth as an equivalent of the present woven fabric, such an interpretation would be improper because Minuth emphasizes that the coating, of itself, provides no 3D structure either. The coating is said to “offer the possibility of three-dimensional spreading of multiplication of cells,” ostensibly in a stochastic fashion. Col. 2, lines 10-14. Indeed, Minuth appears to capitalize on the notion that certain material that enable wound healing could promote cell growth *in vitro*. However, the use of such materials in a framework—a three dimensional biodegradable framework no less—is not taught or suggested by Minuth. Hence, the design of the devices of the claimed invention does provide a biodegradable 3D structure, which can later be degraded and replaced by a more “natural” structure produced by the growing cells. By contrast, the carrier of Minuth, being of non-degradable polymer, remains with time.

In sum, even assuming, *arguendo*, that the Examiner maintains the instant combination as proper, such a combination still fails to meet each and every limitation of the claimed invention, namely, a woven fabric comprising a biodegradable polymer. As well, for the reasons expounded above, Minuth neither teaches nor suggests the use of biodegradable polymers in the manufacture of a woven fabric “carrier.” Applicants further submit the combination of the additional cited references fail to cure the deficiencies of MacDonald, Martinez and/or Minuth. For at least these reasons, Applicants respectfully solicit the withdrawal of the Section 103 rejections.

Double patenting

Claims 6, 7 and 10-13 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-3, 23 and 29 of co-pending Application No. 11/226351 for the reasons of record. Applicants respectfully disagree with this rejection, but in any event, request that the Examiner hold this “provisional” rejection in abeyance until claims are otherwise found allowable in the present case or patented in the co-pending case. *See*, M.P.E.P. § 804 (I)(B).

Applicants believe that the present application remains in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.


The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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